

Replaced by Article 34

WO 03/103737

PCT/NZ03/00116

Rec'd PCT/PTO 10 DEC 2004 10/517378

CLAIMS

1. A keratin-containing material for use in the preservation, restoration and development of form and function of bone.
5
2. A porous keratin material for use in the replacement and augmentation of bone.
3. A dense keratin material for use in bone fixation and immobilization.
10
4. A material according to any of claims 1, 2 or 3 wherein the keratin is S-sulfonated.
5. A material according to any one of claims 1-4 wherein the keratin is enriched in intermediate filament protein.
15
6. The keratin material of claim 5 which is prepared by compression of solid keratin powder.
7. The dense material of claim 3 which is prepared by compression of keratin film.
20
8. The material of any one of claims 1-7 that contains up to 60% calcium salts.
9. The material of any one of claims 6 or 7 wherein compression is followed by freeze-drying of solid keratin.
25
10. A use of a dense keratin material in the manufacture of a medical support or scaffold in the preservation, restoration and development of form and function of bone.
- 30 11. The use according to claim 10 wherein the keratin material is S-sulfonated.
12. The use according to claim 10 or 11 wherein the keratin is enriched in intermediate filament protein.
- 35 13. A method of forming a dense material of S-sulfonated keratin material into an orthopaedic product comprising:

BEST AVAILABLE COPY

- a) compressing keratin in the presence of heat and water;
- b) strengthening the material;
- c) washing the material to remove residual chemicals; and
- d) drying the material.

5

14. A method for forming a dense material of S-sulfonated keratin into an orthopaedic product comprising:

- a) strengthening the keratin-containing starting material;
- b) washing the material to remove residual chemicals;
- c) drying the material; and
- d) compressing keratin in the presence of heat and water.

10

15. A method of forming a porous S-sulfonated enriched keratin material comprising:

- a) compressing keratin in the presence of a soluble porogen;
- b) removing the porogen and strengthening the material;
- c) washing the protein material; and
- d) freeze drying the material.

15

20. A method according to claim 15 wherein the porogen is selected from sodium chloride or another biocompatible salt, or glycerol or another biocompatible solvent.

25

17. A method according to any one of claims 15-16 wherein the amount and nature of porogen is controlled to select the pore sizes and allow the infiltration of osteoprogenitor cells to facilitate the colonization of keratin material when implanted.

30

18. A method according to any of claims 13-17 further including the addition of hydroxyapatite to the keratin starting material.

35

19. A method according to any one of claims 13-18 wherein the keratin is enriched in intermediate filament protein.

20. A keratin material prepared by the method of any one of claims 13-19.

35

21. A biocompatible material in the form of a porous keratin that is enriched in intermediate filament protein for use in bone replacement / augmentation therapy.

22. A biocompatible material according to claim 21 wherein the keratin is S-sulfonated.

5 23. A biocompatible material according to claim 21 or 22 which contains up to 60% calcium salts.

10 24. A biocompatible material according to any one of claims 21-23 wherein the material is prepared by compression of solid keratin powder.

25. A biocompatible material according to claim 24 wherein compression is followed by freeze-drying.

15 26. A biocompatible material according to any one of claims 21-25 wherein the material is prepared from a solution of keratin.

27. A biocompatible material according to claim 26 wherein the solution of keratin is freeze-dried.

20 28. An orthopaedic medical material manufactured from biocompatible keratin material for treatment of fractures by internal fixation as well as fixation and immobilisation of bone segments.

25 29. An orthopaedic medical material according to claim 28 which is manufactured from S-sulfonated keratin material.

30 30. An orthopaedic medical material according to claim 28 or 29 wherein the keratin material is enriched in intermediate filament protein.

31. An orthopaedic medical material according to any one of claims 28-30 prepared by compression of solid keratin powder.

35 32. An orthopaedic medical material according to any one of claims 28-30 prepared by compression of keratin film.

33. An orthopaedic medical material according to any one of claims 28-30 prepared from a solution of keratin.

5 34. An orthopaedic medical material according to any one of claims 28-30 that contains up to 60% calcium salts.

10 35. An orthopaedic medical material according to any one of claims 31-33 wherein the keratin is freeze dried after compression.

36. An orthopaedic material according to any one of claims 28-35 made according to the method of any one of claims 13-19.

15 37. A method of reforming S-sulfonated keratin enriched in intermediate filament protein into a tough, dense biocompatible material for use as an internal fixation appliance in the treatment of bone fractures.

38. A method according to claim 36 wherein the keratin is enriched in intermediate filament protein.

20 39. A method according to claim 37 that includes compressing the biocompatible protein in the presence of moisture and chemicals.

40. A method according to claim 39 wherein heat is also used to form a desired shape.

25 41. A method according to any one of claims 37-40 that also involves the controlled use of reducing agents to remove the sulfonate group from the S-sulfonated keratin and reform the disulfides originally present in the native keratin.

30 42. A biocompatible keratin enriched material when produced according to any one of claims 37-41.

35 43. An orthopaedic material according to claim 28 wherein the material is a plate, pin or screw.